

stranded structure by treating the DNA complex having the three-stranded structure with an endonuclease, inserting said treated DNA complex into cells, and culturing the transformant thus obtained to amplify DNA.

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15. (Twice Amended) A DNA constituent comprising at least one three-stranded structure comprising a single-stranded region and a double-stranded region which comprises a sequence that is homologous to said single-stranded region, wherein one double-stranded DNA segment which is between two three-stranded structures confers the ability of auto-replicating within competent cells, and the other double-stranded DNA segment comprises the whole or part of the gene to be cloned.

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

I. CLAIM STATUS & AMENDMENTS

As correctly stated in the Official Action Summary, claims 1-22 were pending in this application when last examined.

By the present amendment, Applicants hereby cancel claims 10, 11, and 20 without prejudice or disclaimer to the subject matter recited therein. Applicants reserve the right to file a continuation or division application on any canceled subject matter.

The present amendment also amends claims 1, 2, and 12-15. Support for the amendments can be found throughout the Specification. For instance, support for the amendment to claim 1 can be found, at least, in original claim 1 and in the Specification, at least, at page 12, lines 12-20. Support for the amendments to claims 2, 12-14 can be found, at least, in original claims 2, 12-14. Support for the amendment to claim 15 can be found, at least, in original claim 20. Accordingly, no new matter has been added by this amendment. Applicants submit that none of these amendments are intended to narrow the scope of any element of the claims.

Upon entry of the present amendment, claims 1-9, 12-19, 21, and 22 will be pending in this application.

II. FORMAL MATTERS

A. Priority

Applicants hereby note the Examiner's acknowledgment of Applicants' claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). Official Action Summary, item 13.

B. Rejections & Objections Withdrawn

Applicants acknowledge the Examiner's withdrawal of the rejection of claims 1-11 and 13-19 under 35 U.S.C. § 102(b) as allegedly anticipated by Ferrin et al. (WO 97/04111). See May 20, 2002, page 2.

Applicants acknowledge the Examiner's withdrawal of the rejection of claim 1 under 35 U.S.C. § 103(a) as allegedly unpatentable over Williams et al. in view of

Camerini-Otero et al. (A) ANNU. REV. GEN., 29:509-52, 1995 and Camerini-Otero et al.

(B) (U.S. Patent No. 5,460,941). See May 20, 2002, page 2.

Applicants acknowledge the Examiner's withdrawal of the rejection of claims 1-22 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite in response to the Amendment and Reply filed July 27, 2001. See May 20, 2002, page 2.

Applicants acknowledge the withdrawal of the objection to the Specification and the objection to claims 2 and 21 in view of the July 27, 2001 Amendment and Reply.

III. DOUBLE PATENTING REJECTIONS

A. Statutory Type Double Patenting

Claim 1 stands provisionally rejected under 35 U.S.C. § 101 as allegedly claiming the same invention as that of claim 1 of co-pending Application Serial No. 09/549,949. See May 20, 2002 Official Action, page 2. Applicants respectfully request that the Examiner hold this rejection in abeyance until subject matter in the present application is deemed allowable.

B. Non-Statutory Double Patenting

Claims 2-9 stands provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-11 of co-pending Application Serial No. 09/549,949 in view of Ferrin et al. See May 20, 2002 Official Action, page 2. Applicants respectfully request that the Examiner hold this rejection in abeyance until subject matter in the present application is deemed allowable.

IV. REJECTION UNDER 35 U.S.C. § 102 (NEW REJECTION)

Claims 1-22 stand newly rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Fujiwara et al., NUCLEIC ACIDS RESEARCH, 26(24):5728-5733 (1998) (hereinafter "Fujiwara A") or Fujiwara et al., NUCLEIC ACIDS RESEARCH, 26(24):5734-5737 (1998) (hereinafter "Fujiwara B"). See May 20, 2002 Official Action, pages 2-3.

Applicants respectfully traverse this rejection. Applicants submit that the cited art references fail to anticipate the claimed invention because they fail to teach each and every element of the claimed invention. To anticipate a claim, a single prior art reference must teach, either expressly or inherently, each and every element of the claimed invention. See M.P.E.P. § 2131; Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986). As illustrated below, Fujiwara A and Fujiwara B fail to teach each and every limitation of the claimed invention.

Applicants submit that the teachings of Fujiwara A and Fujiwara B are very different from the claimed invention. Fujiwara A and Fujiwara B disclose a method for ligating a double-stranded (hereinafter "ds") DNA and another ds DNA having a single-stranded (hereinafter "ss") DNA end using a homologous protein. In the ligation method of the Fujiwara references, the ligation is maintained (stabilized) by the formation of a covalent bond between DNA ends that were reacted with the homologous protein using DNA ligase. In contrast, the method of the present invention differs fundamentally from this teaching in that the ligation of the claimed invention is maintained (stabilized) without

using DNA ligase via the formation of a three-stranded DNA structure that forms as a result of the homologous protein acting on the two DNA ends that are to be ligated. In this regard, Applicants direct the Examiner's attention to the instant Examples which prove that the ligation is maintained (stabilized) even without using DNA ligase. *lim not in claims*

In addition, the claimed invention differs from the teachings of Fujiwara in that the claimed method has a unique function — the three-stranded DNA structure can be converted into a ds DNA structure comprising no nicks by introducing the DNA complex having the three-stranded DNA structure into cells, and then replicating it therein. This unique function of the claimed invention is neither disclosed nor suggested by the Fujiwara references.

Furthermore, unlike the methods described in the Fujiwara references, the instant invention has superior effects in that it performs the conversion of a three-stranded DNA into a ds DNA having no nicks within the cells. This unique property means that the instant invention does not require the extra complicated procedures needed in the prior art to perform a ligation reaction with DNA ligase. *lim not in claims*

Therefore, the teachings of Fujiwara and the present inventions are very different. Thus, since the Fujiwara references fail to teach or suggest each and every element of the claimed invention, these references do not anticipate the claimed invention. Therefore, Applicants respectfully request withdrawal of this rejection.

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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Attachment to Amendment

Marked-up Copy of Amended Claims 1, 2, and 12-15

1. (Twice Amended) A method of ligating a double-stranded end of a double-stranded DNA and a single-stranded end of another double-stranded DNA, wherein the method comprises:
 - a) contacting, in the presence of a homologous recombinant protein, the single-stranded end of said other double-stranded DNA and the double-stranded end of said double-stranded DNA, wherein said double-stranded DNA comprises a sequence that is homologous to the nucleotide sequence of said single-stranded end, to form a three-stranded [DNA structural complex] structure comprising said single-stranded end and said double-stranded end, and
 - b) completing the ligation by converting the three-stranded structure into a double-stranded structure by inserting the DNA complex comprising the three-stranded structure into cells.

2. (Twice Amended) The method of ligation of claim 1, wherein said three-stranded DNA structural complex is a circular DNA complex having a three-stranded structure in two positions, wherein said three-stranded structure is made by either the ligation of:

- a) a double-stranded DNA comprising a single-stranded region at both ends, and
- b) a double-stranded DNA having at both ends a double-stranded region comprising sequences that are respectively homologous to said single-stranded nucleotide regions in a); or [said three-stranded structure is made by] the ligation of:
- c) a double-stranded DNA comprising a single-stranded region at one end and a double-stranded region at the other end, and
- d) a double-stranded DNA comprising a double-stranded region at one end having a sequence that is homologous to the nucleotide sequence of said single-stranded nucleotide region in a) and a single-stranded region at the other end comprising a sequence that is homologous to the nucleotide sequence of the double-stranded nucleotide region in a).

12. (Twice Amended) The method of ligation of claim [11] 1, wherein the insertion of the DNA complex comprising a three-stranded structure into cells is done by electroporation.

13. (Twice Amended) The method of ligation of claim [10] 1, wherein the conversion of the three-stranded structure to a double-stranded structure is done by a nucleic acid modification enzyme.

14. (Twice Amended) The method of ligation of claim 1, wherein said method further comprises steps of converting the three-stranded structure into a double-stranded structure by treating the DNA complex having the three-stranded structure with an endonuclease, inserting said treated DNA complex into cells, and culturing the transformant thus obtained to amplify DNA.

15. (Twice Amended) A DNA constituent comprising at least one three-stranded structure comprising a single-stranded region and a double-stranded region which comprises a sequence that is homologous to said single-stranded region, wherein one double-stranded DNA segment which is between two three-stranded structures confers the ability of auto-replicating within competent cells, and the other double-stranded DNA segment comprises the whole or part of the gene to be cloned.